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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,704	07/25/2001	Stig Jansson	CU-2513 RJS	2557

26530 7590 03/27/2008

LADAS & PARRY LLP
224 SOUTH MICHIGAN AVENUE
SUITE 1600
CHICAGO, IL 60604

EXAMINER	
WINSTON, RANDALL O	

ART UNIT	PAPER NUMBER
1655	

MAIL DATE	DELIVERY MODE
03/27/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/807,704	JANSSON ET AL.	
	Examiner	Art Unit	
	RANDALL WINSTON	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *35-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/18/2007 has been entered.

Claims 35-52 and new claims 53-54 will be examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 53-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 53 recites the term “estimating a first yield.” No objective criterion is provided in the specification or claim to apprise one of skill in the art of the meaning of “estimating a first yield.” There is no definition of “estimating a first yield” in the claims or specification to apprise one of skill in the art with an unambiguous meaning of the claimed invention. Accordingly the metes and bounds of this phrase are not clearly delineated (i.e. How is the estimating being performed and/or done?)

Claim 53 recites the term "calculating another yield." No objective criterion is provided in the specification or claim to apprise one of skill in the art of the meaning of "calculating another yield." There is no definition of "calculating another yield" in the claims or specification to apprise one of skill in the art with an unambiguous meaning of the claimed invention. Accordingly the metes and bounds of this phrase are not clearly delineated (i.e. How is the calculating performed and/or done?)

Claim 53 recites the term "optimizing an extraction temperature." No objective criterion is provided in the specification or claim to apprise one of skill in the art of the meaning of "optimizing an extraction temperature." There is no definition of "optimizing an extraction temperature" in the claims or specification to apprise one of skill in the art with an unambiguous meaning of the claimed invention. Accordingly the metes and bounds of this phrase are not clearly delineated (i.e. Is applicant optimizing an extraction temperature for the biological material or the treated biological material? Clarification is needed.)

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under 35 U.S.C. 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 35-52 stand rejected under 35 U.S.C. 1039a) as being unpatentable over Jannson et al. (No. Patent application number 1993 3009) in view of Keyes (US 4,713,335) and for the reasons set forth in the previous Office action which are restated below.

Applicant claims an improved oil separation process for production of a composition free of denatured proteins from a material comprising lipids and proteins, said material having a biological origin, the process comprising the steps of predetermining a denaturing temperature of a material comprising lipids and proteins (i.e. predetermining temperature is determined by visual observation and/or viscosity measurement), freezing and mechanically treating the material (also adding pretreatment compounds prior to mechanically treating), heating the material to a working temperature, wherein said working temperature is below the denaturing temperature and separating a composition comprising protein and at least one of the group consisting of fat and lipid, said composition being free of denatured proteins.

Jansson et al teach (see, e.g. entire document) a process for separating elements from the claimed biological material compound and/or composition (i.e., fish or marine material) to obtain high yields of non-denatured protein (i.e. free of denatured proteins), fats or lipids and intrinsically producing grax and trace elements when performing Jansson's separation step whereas Jansson's claimed process would also intrinsically produce the claimed composition comprising non-denatured protein (i.e. free of denatured proteins) and at least one of the group consisting of fat and lipid when such steps are performed as the steps of freezing and mechanically treating the

biological material (i.e. please note mechanically treating by grinding and also the reference states one of ordinary skill in the art would add pretreatment compounds such as solvents and/or enzymes because enzymes protect the lipids against oxidation within the process and the reference also states adding antioxidants wherein the process, see, e.g. page 3 and 4) at the same claimed freezing temperature interval (i.e., freezing at –6 degree Celsius); subsequently heating the biological material to a temperature as not to denature the protein contained within the biological material (i.e. please note on page 9 of Jansson et al's specification, it states that the heating should be done at low temperatures not to denature the protein), and then separating and isolating high yields of lipids, fats or non-denatured protein whereas Jansson's process intrinsically produce the claimed composition comprising non-denatured protein (i.e. free of denatured proteins) and at least one of the group consisting of fat and lipid. Jansson's process is also done under a condition of a vacuum.

Jansson et al. do not expressly teach claims 49-50 of predetermining the denaturing temperature of the material is determined by visual observation (i.e. claim 49) and/or viscosity measurements (i.e. claim 50).

It would have been obvious to one of ordinary skill in the art at the time the invention was created to modify Jansson et al's process to include the predetermining step of visual observation to determine the denaturing temperature of a material because visual observation would be an intrinsic feature within '009 to aid in monitoring the temperature within the process in order not allow the protein to become denatured. (please note: predetermining the denaturing temperature by visual observation prior to

performing the other claimed steps, especially the heating step in order not to denature the protein would be an intrinsic feature within '009 process. On page 9 lines 2-5 of '009, it states that low-temperatures should be used within its process not to denature the proteins. Thus, a predetermining step would be an intrinsic feature within '009 process because '009 discloses monitoring its process's temperature by utilizing a low temperature for the purpose of not to denature the protein.)

Furthermore, Keyes beneficially teaches (see, e.g. column 5 lines 29-35) that viscosity measurements are used to monitor protein denaturation and/or determine the denaturing temperature within a material.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Jansson et al.'s process to include the disclosure of viscosity measurements are used to monitor protein denaturation and/or determine the denaturing temperature within a material as taught by Keyes' because the combined teachings would create a method of separating elements from a material wherein the elements separated do not contain denatured proteins. The adjustment of conventional working conditions (e.g the heating step is performed continuously and/or semi-continuously, the isolation step and the freezing rate and/or time period), is deemed merely a matter of judicial selection and routine optimization which is well within the purview of the skilled artisan. Moreover, as the references indicate the various different steps used by the claimed method is result variable, therefore, they could be routinely optimized by one of ordinary skill in the art of practicing the invention disclosed by the references. (e.g. the ordered pretreatment steps, the order of the predetermining step,

especially before heating and the ordered mechanically treating steps occurs before said freezing step) (Please note the selection of any order of performing process steps is *prima facie* obvious in the absence of new or unexpected results. (see, e.g., *Ex parte Rubin*, 128 USPQ 440, 1959, and *In re Burhans*, 154 F.2d 690, 69 USPQ 330-CCPA 1946) MPEP 2144.04)

Accordingly, the invention as a whole is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Applicant's argument filed on 12/18/2007 has been carefully considered but it is not deemed persuasive. Applicant argues the presently presented data, combined with the fact that the industry has not previously attempted to perform the oil separation at such elevated temperatures despite the significant advantages gains from this, should prove that such a separation indeed is novel and nonobvious which should establish inventive merit.

Although Applicant argues the presently presented data, combined with the fact that the industry has not previously attempted to perform the oil separation at such elevated temperatures despite the significant advantages gains from this, should prove that such a separation indeed is novel and nonobvious which should establish inventive merit, Applicant argument is not found persuasive because it would have been obvious to one of ordinary skill in the art at the time the invention was created to modify Jansson et al's process to include result-effective conventional working conditions such as the

extraction modification of the biological material to elevated and/or higher extraction temperatures whereas an elevated and/or higher extraction temperature of the biological material would obviously produce more oil is deemed merely a matter of judicial selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, the invention as a whole is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RANDALL WINSTON whose telephone number is (571)272-0972. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christopher R. Tate/
Primary Examiner, Art Unit 1655